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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/916,169 | 12/17/1996 | STEPHEN M. ANDERTON | 961125 | 5487 |

7590 12/04/2001

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EXAMINER

NOLAN, PATRICK J

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 12/04/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------------|---------------------------------|
| Office Action Summary | Application No. 08/716,169 | Applicant(s) Anderton et al. |
| | Examiner Patrick J. Nolan | Art Unit 1644 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Sep 20, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 24-30 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 24-30 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) Interview Summary (PTO-413) Paper No(s). _____

19) Notice of Informal Patent Application (PTO-152)

20) Other: _____

Part III DETAILED ACTION

1. This application is a 371 of PCT/NL95/00108.
2. Claims 24-30 are pending.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-20-01 has been entered.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 24-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's specification has no working examples demonstrating the enablement of the claimed invention.

In endogenous peptide therapy, the goal of peptide immunotherapy of T-cell-mediated autoimmunity is to induce anergy in self reactive T cells. However Wraith et al., (U, Cell 59: 247-255, 1989) teach the "Inhibition of the response restricted by one Class II molecule may lead only to the escape to an autoimmune response to a separate epitope restricted by a different class II molecule." (page 253 column 1, in particular).

Furthermore, Tisch et al., (V, P.N.A.S. 91:437-438) teach that treating an ongoing T-cell-mediated autoimmunity by administering an antigen peptide may have an immunizing effect and exacerbate the disease condition (page 437, column 3, in particular). Since applicant has not provided any working examples of the efficacy of the peptides in treating already established multiple sclerosis patients, it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention and this is not sanctioned by the statute.

Lastly, Applicant has not enabled the recitation of the terms "peptides comprising at least 5 amino acids which are identical with corresponding amino acids in the same relative position in a T cell epitope of said mammalian stress protein". The breadth of Applicant's claims would encompass limitless amounts of possible peptides. Applicant has not demonstrated that any peptides out of this entire genus meets the limitations of their claims. The state of the art as taught by Karin et al., demonstrates that a substitution of an phenylalanine with alanine (i.e. a conservative amino acid substitution) at position 89 resulted in an increase in T cell proliferation, binding affinity of the peptide and induction of EAE in rats (a animal model of multiple sclerosis), while the same amino acid substitution, an phenylalanine for an alanine, at position 90, resulted in the exact opposite results, decreased binding, T cell proliferation and no induction of EAE (see Table 1, in particular). What the results of the Karin et al., article indicate is that the effects of amino acid changes on peptide-MHC binding, T cell proliferation and in vivo effects of said peptides is unpredictable. Since Applicant has provided little guidance in their specification as to how one of skill in the art would overcome such unpredictability of the effects amino acid changes have on the peptides, it would require an undue of experimentation to practice Applicant's claimed invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan
Patrick J. Nolan, Ph.D.
Patent Examiner, Group 1640
December 3, 2001